

Nuclear Regulatory Commission

§ 32.55

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.101, Schedule B, of this part.

[30 FR 8192, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 43 FR 6923, Feb. 17, 1978]

§ 32.54 Same: Labeling of devices.

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.1901 of this chapter, such other information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:¹

The receipt, possession, use, and transfer of this device, Model* _____, Serial No.* _____, containing _____ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL

(Name of manufacturer, assembler, or initial transferor.)*

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor,

(ii) The type and quantity of radioactive material,

(iii) The model number,

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

[33 FR 16331, Nov. 7, 1968, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 63 FR 39483, July 23, 1998]

§ 32.55 Same: Quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (b)(1) of this section shall be measured for tritium or promethium-147 content by an apparatus that has been calibrated to

¹ Devices licensed under § 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.